IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SPD SWISS PRECISION DIAGNOSTICS GMBH, v. CHURCH & DWIGHT CO., INC. AND CONSOLIDATED ACTION	Case Nos.: 3:09-CV-01802 (MAS)(TJB) 3:10-CV-00276 (MAS)(TJB) *Document Electronically Filed* Oral Argument Requested Return Date: September 17, 2012

CHURCH & DWIGHT CO., INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION[1]

Church & Dwight Co., Inc. ("C&D") and SPD Swiss Precision Diagnostics GmbH ("SPD") both market home pregnancy and home ovulation test kits. (Feldman Dec. ¶3)[2] C&D's flagship brand is "First Response" ("FR"); SPD's is "Clearblue." SPD and one of its two parent companies, Inverness Medical Innovations, Inc. ("Inverness") (now called Alere, Inc.), dominate the home pregnancy test market. Their only competitor is C&D. (*Id.* ¶3)

This litigation is ostensibly about alleged false advertising, but it is really part of a larger campaign of anti-competitive conduct by SPD and Inverness to stifle C&D's gains in the home pregnancy test market -- gains that C&D has achieved because it has better products. Indeed, in 2008 the Federal Trade Commission ("FTC") charged Inverness with engaging in unlawful conduct designed to injure C&D in the market for "digital" home pregnancy tests. (Vinti Dec. Exs. 2 and 3) Inverness opted to settle the FTC's charges, rather than defend against them. (*Id.* Ex. 2 and 4)

This litigation is wholly consistent with the anticompetitive conduct investigated by the FTC. When SPD launched this litigation, C&D had been making the core advertising challenged by SPD in the First Action for years. That advertising statement is one promoting the ability of two FR pregnancy test kits to detect pregnancy five days before the day a woman misses her menstrual period. That statement had been included on the packaging for the then-marketed FR "analog" pregnancy test ("FR Analog 5-day") since at least as early as April 2006, nearly *three*

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[1] The above-captioned actions, Case No. 09-01802 (the "First Action") and Case No. 10-00276 (the "Second Action"), are consolidated for pretrial purposes. The First Action was filed by SPD in the United States District Court for the Northern District of California and transferred to this Court on Church & Dwight's motion, which SPD opposed.

[2] Church & Dwight submits the following accompanying declarations: Declaration of Stacey Feldman ("Feldman Dec."); Declaration of Baldassare Vinti ("Vinti Dec."); the Declaration of Albert Nazareth, Ph.D. ("Nazareth Dec."), Declaration of Pasquale Patrizo, M.D.("Patrizio Dec."), Declaration of Ann Gronowski, Ph.D. ("Gronowski Dec."); and, Declaration of Anthony Scialli, M.D. ("Scialli Dec.")

years before SPD filed the First Action in January 2009. (Feldman Dec. ¶5)[3] C&D had also been making the same advertising statement on the packaging for its FR "digital" pregnancy test ("FR Digital 5-day") for nearly a year before the First Action was brought by SPD challenging that statement. (*Id.*)

SPD waited until two days after the end of the public comment period for the Consent Order that its parent Inverness entered into with the FTC before initiating this litigation and moving for an "emergency" injunction. (Vinti Dec. Ex. 4) The relief that SPD so urgently sought -- after sitting on its purported claims literally for years while Inverness worked out a settlement with the FTC -- was to pull FR Digital 5-day off store shelves and effectively drive C&D out of the market for digital home pregnancy tests. That was precisely the goal the FTC had charged Inverness with illegally attempting to achieve. (*Id.* Ex. 2 and 3) Doubtless, SPD chose to wait until the ink was dry on the Consent Decree before filing a suit that the FTC would see as one more step to cripple Inverness' and SPD's only competitor.

Consistent with its anti-competitive aims, after this litigation began SPD made known that it would try to prevent C&D from marketing FR Analog 6-day, even though that product had been cleared by the U.S. Food & Drug Administration ("FDA," which regulates home pregnancy tests) for the intended use of detecting pregnancy as early as 6 days before the day of a woman's missed menstrual period ("MMP").[4] SPD and Inverness offer no comparable product to consumers (Feldman Dec. ¶7), and they plainly saw C&D's "6 day" test with its advanced technology as a threat to their market domination. In the face of SPD's threat to sue, C&D

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[3] FR Analog 5-day was replaced in early 2010 with an improved FR analog pregnancy test ("FR Analog 6-day"). (*Id.* ¶7) That product is advertised by C&D as being able to detect pregnancy 6 days before the day a woman misses her period. (*Id.*)

[4] FR Analog 6-day is the only product on the market cleared for that use. (*Id.*) FR Digital 5-day and FR Analog 5-day were cleared by the FDA for the intended use of detecting pregnancy 5 days before MMP.

commenced the Second Action seeking a declaratory judgment that its advertising of FR Analog 6-day's ability to detect pregnancy 6 days before MMP was truthful and lawful. SPD counterclaimed and brought a second preliminary injunction motion.

Tellingly, after much briefing and two hearings, SPD abandoned its preliminary injunction motions before Judge Wolfson could render a decision. However, as was reflected in the proposed orders SPD filed in connection with those motions, SPD seeks through this litigation to bar C&D from making *any* advertising statement that: (a) FR Analog 6-day is "accurate or effective at detecting pregnancy when used six days prior to" MMP; and (b) C&D's 5-day tests are "accurate or effective at detecting pregnancy when used five days prior to" MMP. (Vinti Dec. Ex. 5 and at ¶1) An injunction barring C&D from making those claims would, of course, dramatically impair its competitive position. SPD has therefore poured enormous effort and expense into this lawsuit in an attempt to achieve through litigation the very perpetuation of its and Inverness' market dominance that had sparked the FTC's concern.

Now, after two (abandoned) preliminary junction motions, countless party and expert declarations, document discovery that involved exchanging well over a million pages, 18 fact depositions, 23 expert reports, 9 expert depositions, countless discovery motions and legal fees and costs running in the millions of dollars, what, exactly, can SPD point to in the record to prove (as is its burden) that C&D's advertising statements are false? After all this time, money and effort, SPD relies solely on the testimony of a single "expert," hired for this litigation, who opines, without any scientific basis or support, that C&D's methodology for estimating the day of a woman's expected menstrual period ("EMP", which is the day before the day of MMP) is incorrect. According to that contrived theory, C&D allegedly exaggerates the number of days before MMP its pregnancy tests can detect pregnancy.

As we demonstrate below, such a challenge to C&D's methodology is not even properly before this Court in light of FDA's clearance of the FR products to be marketing for their intended use (*i.e.*, to detect pregnancy as early as 5 and 6 days before MMP). Put simply, SPD is asking this Court to second-guess FDA's judgment. The cases make clear that this Court should not indulge that effort. But even putting aside the impropriety of SPD's attempt to have this Court countermand the FDA, the naked opinion of its expert cannot possibly sustain its burden of proof. As we show in great detail in our companion motion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, SPD's expert's opinion is inadmissible and, under Third Circuit precedent, therefore cannot raise a triable issue of fact.

PRELIMINARY STATEMENT AND SUMMARY OF ARGUMENT

The law in this Circuit is clear that it is the burden of the party challenging an advertising statement affirmatively to prove falsity, not merely that the substantiation for the statement is inadequate. Simply put, it is not sufficient for the plaintiff to argue that the advertiser's substantiation "isn't good enough." Moreover, a challenged advertising statement can only be "literally false" if it is both unambiguous and false. If a challenged statement reasonably can be interpreted, in context, as conveying multiple messages at least one of which is truthful, then the challenger must show that a substantial percentage of consumers actually perceived the allegedly false message. Such evidence almost always takes the form of a consumer perception survey.

Below and in our *Daubert* motion we address SPD's core allegation that C&D's 6-days and 5-days before MMP advertising statements are false. Although it is not C&D's burden to prove that those statements are substantiated, the fact is they are well substantiated by multiple clinical trials, including the study results C&D submitted to FDA in connection with FDA's clearance of the FR pregnancy tests for the intended use of detecting pregnancy 6 and 5 days

before MMP. The results of the clinical studies provided to FDA were confirmed by a subsequent independent study designed and supervised by Dr. Anthony Scialli, a professor at the George Washington and Georgetown University Schools of Medicine.

In their respective clinical testing, C&D and SPD each used the urines of newly pregnant women to study the efficacy of their pregnancy tests in detecting pregnancy on days prior to the day of EMP and MMP. Because women do not have a menstrual period during the menstrual cycle in which they become pregnant, any study to assess pregnancy test efficacy prior to the day of EMP necessarily must utilize a method to estimate the day of EMP. Both parties use a method that relies on the detection of a "biomarker," a hormone known as luteinizing hormone (or "LH" for short). SPD contends, however, that C&D's method of estimating the day of EMP is materially different than the method Dr. Barnhart purportedly favors. But for SPD to prove that C&D is falsely claiming pregnancy detection efficacy 5 or 6 days before MMP, it must show that C&D's method for estimating the days of EMP is *wrong* not merely that it is *different from* the method Dr. Barnhart claims to prefer. SPD cannot sustain that burden.

C&D's method of estimating the day of EMP is supported by a highly credentialed expert -- Dr. Pasquale Patrizio, a reproductive endocrinologist at Yale University -- who opines, based on a wealth of peer-reviewed scientific literature discussed in our *Daubert* motion, that this method is reasonable and appropriate. However, as noted, SPD expert, Dr. Kurt Barnhart, opines that C&D's method "is a departure from accepted scientific standards" (Vinti Dec. Ex. 11 at ¶5) Dr. Barnhart claims that C&D's method results in "inflated" pregnancy detection rates in its clinical testing and that, if C&D had estimated the day of EMP using the method preferred by Dr. Barnhart, the results of C&D's clinical testing would actually prove that FR Analog 6-day is not effective in detecting pregnancy 6 days before MMP and FR Digital 5-day is not effective in

detecting pregnancy 5 days before MMP.[5] This is the crux of SPD's case that C&D's 5-days and 6-days advertising statements are false.

Dr. Barnhart's testimony fails to present a genuine issue of material fact for two distinct reasons. First, as we show in our accompanying *Daubert* motion, Dr. Barnhart's opinion is not based on reliable scientific methods and principles. Indeed, among other things, there is no evidence that it is generally accepted in the relevant scientific community, or supported by the peer reviewed literature he purports to rely on or by any other literature disclosed during the expert discovery phase of this litigation. Under Fed. R. Evid. 702 and the Supreme Court and Third Circuit cases construing it, Dr. Barnhart's mere say-so that C&D's method is wrong is insufficient. Dr. Barnhart and SPD must present *facts* demonstrating a consensus in the field of reproductive endocrinology that C&D's method for determining the day of EMP is scientifically inappropriate. They have failed to do so (as we show in detail in the accompanying *Daubert* motion), rendering Dr. Barnhart's opinion inadmissible. Accordingly, SPD cannot raise a genuine issue of material fact as to C&D's correct statements that FR Digital 5-day and FR Analog 5-day can detect pregnancy as early as 5 days before MMP, and that FR Analog 6-day can detect pregnancy up to 6 days before MMP.

In addition, and wholly apart from *Daubert*, the case law prohibits SPD from asking this Court to countermand FDA's clearance of FR Digital 5-day and FR Analog 5-day for the intended use of detecting pregnancy as early as 5 days before MMP and FR Analog 6-day for the intended use of detecting pregnancy as early as 6 days before MMP. If SPD wishes to challenge the efficacy of the products for their intended uses as cleared by the FDA, the forum in which to do so is the FDA, not this Court. This is discussed in Point II of the Argument below.

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[5] In his expert reports, Dr. Barnhart does not make this argument regarding FR Analog 5-day.

SPD alternatively contends that, even if C&D can make *a* 6 days before MMP statement for FR Analog 6-day or *a* 5 days before MMP statement for FR Digital 5-day, the specific statements C&D makes on its product packaging constitute false advertising. These contentions also fail to raise a genuine issue of material fact, as we show in Points III and IV of the Argument below. Specifically, SPD alleges that the statement on the FR Analog 6-day package, "THE ONLY TEST THAT TELLS YOU 6 DAYS BEFORE YOUR MISSED PERIOD[.] See side panel for details" (the "Tells You statement"), constitutes a literally false message that any woman using the product 6 days before MMP will know for certain whether or not she is pregnant. To support this charge, SPD relies on a consumer perception survey conducted by SPD expert Dr. Eugene Ericksen (the "Ericksen survey"). Here again, SPD's arguments fail.

First, when viewed in the context of the product packaging on which it appears (as Third Circuit law requires it to be viewed), the Tells You statement is not, as a matter of law, either literally false or misleading. For that reason alone, the Ericksen survey must be excluded (as we detail in our *Daubert* motion).

A second reason, also detailed in the *Daubert* motion, is that -- just as Judge Wolfson held when she excluded the last false advertising survey Dr. Ericksen prepared for litigation in this District -- the Ericksen survey is inadmissible because it is neither objective nor scientifically reliable. Finally, as further detailed in our *Daubert* motion, even if the Ericksen survey were admissible, the only reasonable interpretation of its results is that they *affirmatively disprove* that charge that the Tells You statement deceives consumers.

Equally meritless is SPD's challenge to the statement on the FR Digital 5-day package, "ACCURATE DIGITAL RESULTS… 5 DAYS SOONER[.] See side panel for details about early testing" (the "Accurate Digital Results statement"). SPD alleges this statement also conveys an unambiguous

message that a woman using the product will know for certain whether or not she is pregnant. However, as with the Tells You statement, the Accurate Digital Results statement is not a literal message of perfect or near-perfect accuracy. To the contrary, the statement is qualified by the information about the product's accuracy at 5 days before MMP, which is fully set forth on the side panel to which consumers are directed. SPD did not even attempt to proffer consumer survey evidence to support its interpretation. Thus, because it is not a literal advertising statement, SPD's challenge to it cannot survive summary judgment.

SPD also challenges as false the statement "Unsurpassed Accuracy" on the FR Analog 6-day package. It is not at all clear what SPD contends is the false message this statement supposedly conveys, as SPD has suggested that it means different things at different times in this litigation. In any case, at most, the statement is susceptible to different reasonable interpretations, one of which is that the product has unsurpassed accuracy when used 6 days before MMP, the only time point mentioned anywhere on the packaging. Given that there is no other product that is FDA cleared to detect pregnancy 6 days before MMP, SPD cannot meet its burden of proving that any other competing product is more accurate at that time point (and, hence, that the "Unsurpassed Accuracy" statement is false). In any case, as Dr. Ericksen conceded, his survey did not prove that "Unsurpassed Accuracy" conveys any false message.

SPD's pleadings also challenge as false and misleading a number of other advertising statements about C&D's FR home pregnancy and home ovulation test products. Each of those challenges should be dismissed on summary judgment because (a) they are not literal claims and SPD has no consumer survey evidence to prove they are misleading, (b) SPD has no evidence to prove them false, and/or (c) they are non-actionable puffery. This is discussed at Points V and VI of the Argument below.

STATEMENT OF FACTS

The Parties and Their Products

C&D (headquartered in Princeton, NJ) and SPD (based in Europe and a joint venture between Inverness and Procter & Gamble) are the two leading marketers of home pregnancy and ovulation tests. (Feldman Dec. ¶¶2 and 3) Home pregnancy tests are intended to tell a woman whether or not she is pregnant. Home ovulation tests are intended to help women become pregnant by identifying the days during their menstrual cycle in which they are most likely to become pregnant. (Nazareth Dec. ¶4)

Home pregnancy tests function by detecting the presence of a placental hormone found in urine called human chorionic gonadotropin (referred to either by the acronym "hCG" or as the "pregnancy hormone"). (Nazareth Dec. ¶5) A woman uses the products either by placing the test stick in her urine stream or by dipping the test stick into a cup containing her urine. (*Id.* ¶7) Both parties market two types of pregnancy tests, called analog (also referred to as "visual") and digital. (*Id.* ¶4) Analog products display results using lines or symbols (*i.e.*, "+" or "-"). (*Id.*) Digital products display results with words. (*Id.*)

Ovulation tests work by a different means. A woman's menstrual cycle is comprised of two phases, the follicular phase and the luteal phase. (Patrizio Dec. ¶4) The luteal phase is generally considered to begin when a woman ovulates (*i.e.*, when a woman's egg is released from her ovary). (*Id.*) The time during a woman's menstrual cycle during which sexual intercourse is most likely to result in conception is the period immediately prior to and including ovulation. (*Id.*) Because it is not possible to determine precisely when a woman ovulates by testing urine samples, researchers have looked for other markers of ovulation present in a woman's urine that would provide a woman seeking to become pregnant with information as to when she is likely to be most fertile. (*Id.*) Over time, a consensus has developed that a good

predictor of ovulation is a substantial elevation over baseline levels of LH. (*Id.*) Home ovulation tests detect this rise, or "surge," in LH levels to predict when a woman is likely to ovulate. (*Id.*)

Clinical Testing of Home Pregnancy Test Products' Ability to Detect Early Pregnancy

The ability of home pregnancy tests to detect hCG in the urines of pregnant women is principally assessed through clinical testing using urines given once daily by women attempting to become pregnant. (Nazareth Dec. ¶9) In a menstrual cycle in which a woman becomes pregnant, she will not have her menstrual period. (Patrizio Dec. ¶9) Thus, since the purpose of the clinical studies is to assess the efficacy of one or more pregnancy tests in detecting hCG in the days prior to the day of the donor's EMP/MMP, it is necessary for the party conducting the study to utilize an appropriate means for estimating the day of EMP/MMP. (Nazareth Dec. ¶9)

The methods both parties have used to estimate the date of EMP/MMP derive from a convention widely accepted by reproductive endocrinologists. This convention is that the day of EMP is generally 14 days after ovulation. (Patrizio Dec. ¶6) In like manner, because (also by convention) the day of MMP is the day after the day of EMP, the day of MMP is generally considered to be 15 days after ovulation. (*Id.*)

It is widely recognized by endocrinologists that a significant rise in LH compared to a woman's baseline level of that hormone is a reasonable predictor of impending ovulation. (*Id.* ¶7) [redacted] urine sample donated by each study subject during the menstrual cycle in which she became pregnant. (Nazareth Dec. ¶10) For each subject, C&D has selected the daily urine sample in which the LH level is at its highest, *i.e.*, "peak," value compared to all of her other daily urine samples as the linchpin for estimating her day of EMP. (*Id.*) In other words, in its clinical studies, C&D estimates the day of EMP for each woman by

adding 15 days to the day on which her LH level was at its peak value. (*Id.*) As noted above, this method is, in the opinion of Yale's Dr. Patrizio, a reasonable and appropriate method for estimating the day of EMP because (as the scientific literature discussed in our *Daubert* motion shows) LH peak generally precedes ovulation by close to a day and ovulation is generally 14 days prior to the day of EMP. (Patrizio Dec. ¶9)

As is detailed in C&D's accompanying *Daubert* motion, Dr. Barnhart opines that C&D's method is wrong because, he claims, 15 days should be added not to the LH peak but rather to the day on which LH levels first begin to rise above baseline (generally known as "the LH surge onset"). In the accompanying *Daubert* motion, we explain why this opinion is inadmissible. Suffice it to say here that his opinion is not based on a permissible reading of any scientific literature or generally accepted practice or principles. It is an opinion based solely on his say-so, as part of his engagement as a litigation expert.

FDA's Regulation of Home Pregnancy Tests and Its Clearance of the FR Tests

The parties' home pregnancy test products are regulated by the FDA as "Class II medical devices." (Nazareth Dec. ¶11) The Medical Device Amendments of 1976, 21 U.S.C. §360c *et seq.*, require any party seeking to market a Class II device to file a "Premarket Notification" (commonly known as a "510(k)" submission) with the FDA. *See* 21 U.S.C. §360(k). The 510(k) submission must demonstrate that the device to be marketed is "substantially equivalent" to an existing legally marketed device (known as a "predicate device"), as described in 21 C.F.R. § 807.92(a)(3). In deciding whether a device is substantially equivalent, the FDA considers the applicant's proposed statement of intended use for the product. *See* 21 C.F.R. § 807.92(a)(4), (5). When a determination of substantial equivalence requires the assessment of performance or efficacy data, the FDA also requires the applicant to include supporting clinical testing data in the 510(k) submission. 21 C.F.R. § 807.92(b).

During the course of a nearly three year application process beginning in 2006, the FDA carefully scrutinized the efficacy of FR Analog 6-day for that product's proposed intended use, namely to detect hCG as early as 6 days before MMP. (Nazareth Dec. ¶19) The FDA's review of the clinical studies, protocols and data submitted by C&D for FR Analog 6-day was extensive and proactive. (*Id.* ¶¶19-23) C&D had numerous telephone conferences and meetings with FDA scientific staff and senior officials to discuss the substantiation of for the product's proposed intended use statement. (*Id.* ¶20)

A key component of the 510(k) submission consisted of clinical studies showing that FR Analog 6-day is effective in detecting hCG as early as 6 days before MMP. (*Id.* ¶¶21-22 and Ex. J at CDSPD0191582) These studies showed that FR Analog 6-day detected hCG in 68% of pregnant women's urines 6 days before MMP (which is 5 days before EMP) when the test was read by inexperienced test readers; when read by experienced laboratory technicians, the positive detection rate at 6 days before MMP was 78%. (*Id.*)

In its 510(k) submission, C&D *explicitly disclosed* that it estimates the day of EMP by adding 15 days to the day of peak LH concentrations:

> The *day corresponding to the sample with the highest hLH (hLH peak)* was designated as the day of ovulation.
>
> * * * *
>
> The OV+15 day would then be the day of the expected period, and the OV+16 day would be the day of the missed period.

(*Id.* ¶25 and Ex. J at CDSPD0191650-51)(emphasis added).

The methodology C&D explicitly disclosed to the FDA is precisely the methodology Dr. Barnhart claims is improper. In any case, knowing exactly how C&D estimated the day of EMP and the results of the clinical studies employing this methodology, the FDA cleared FR Analog 6-day for sale with the following intended use:

> The FR® Early Result Pregnancy Test is an *in vitro* diagnostic home use test device intended for the early detection of pregnancy. The test may detect the pregnancy hormone (hCG), in some cases, as early as 6 days before the missed period (5 days before the expected period).

(*Id.* Ex. I at CDSPD0067405)

In December 2006, C&D filed a 510(k) submission with the FDA seeking clearance to market FR Digital 5-day. (Nazareth Decl. ¶14) A key component of C&D's 510(k) for FR Digital 5-day was a clinical study conducted by C&D that evaluated FR Digital 5-day's ability to detect hCG at various time points, including 5 days before MMP. (*Id.* & Ex. G at CDSPD178) In the study, FR Digital 5-day detected pregnancy in 80% of the tested urine samples of pregnant women taken 5 days before MMP. (Nazareth Decl. ¶¶14 and 24-27 and Ex. K)[6]

The FDA cleared FR Digital 5-day for sale in May 2007. (*Id.* ¶6) FDA's clearance letter included an "Indications for Use" statement that FR Digital 5-day was "intended for the early detection of pregnancy by the lay user *up to five (5) days sooner than the day of the missed period (four (4) days before the day of the expected period)*." (*Id.* at ¶15 & Ex. H)[7] (emphasis added).

The results of the extensive clinical testing submitted to FDA by C&D have since been confirmed by an independent study run by Dr. Scialli, of Georgetown and George Washington

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[6] C&D decided to be very conservative in how to portray the study results on the FR Digital 5-day label. Thus, as an alternative to the 80% positive detection rate result at 5 days before MMP, C&D treated as positive results only those samples for which FR Digital 5-day detected a concentration of hCG above a particular threshold. (*Id.* ¶6 and Ex. K) At the 5 days before MMP time point using this conservative calculation, FR Digital 5-day detected hCG in 58% of the urine samples 5 days before MMP. (*Id.*) C&D disclosed both the 80% and 58% figures to the FDA but proposed, and the FDA accepted, that only the 58% figure appear on the package label. (*Id.*)

[7] FR Analog 5-day was also cleared by FDA for the intended use of detecting pregnancy "by the lay user up to four (4) days prior to the expected menses." (Nazareth Dec. ¶13 and Ex. F) C&D's 510(k) submission for FR Analog 5-day included data of clinical testing showing that FR Analog 5-day detected hCG in 69% of the urine samples given by pregnant women at 5 days before MMP. (*Id.* ¶12 and Ex. E at CDSPD0002725 at Table 2A)

Universities. In that study (Sciall Dec. Ex. A), two models of FR Digital 5-day (provided to C&D by different suppliers) were tested. One model detected hCG in 91.7% of the urine samples given at 5 days before MMP, and the other model detected hCG in 83.3% of the urine samples given at 5 days before MMP. (*Id.* at ¶8 at 7, Tables 3 & 4) Dr. Scialli's study also tested SPD's Clearblue digital product. The two models of FR Digital outperformed Clearblue digital, which SPD advertises as being effective in detecting pregnancy 5 days before MMP. (*Id.* at Table 1) The method for estimating EMP in the study was the same for all products tested. (*Id.* at ¶8) Since in a truly "apples to apples" test, using the same methodology for each product, the FR products outperformed SPD's Clearblue product in detecting pregnancy 5 days before MMP, Dr. Barnhart's criticism of C&D's EMP estimation methodology (even if it had merit) is perforce irrelevant: if SPD can make the claim that Clearblue is effective in detecting pregnancy 5 days before EMP, C&D surely can make the same claim for its 5-day products.

Dr. Scialli also tested C&D's FR Analog 6-day product. It was found to detect pregnancy in 91.5% of the urine samples given at 6 days before MMP. (*Id.* at 8, Table 2)

The Advertising Statements Challenged By SPD

As noted, SPD's main attack in this litigation is to challenge C&D's right to make *any* statement that FR Digital 5-day is effective in detecting pregnancy 5 days before MMP and that FR Analog 6-day is effective in detecting pregnancy 6 days before MMP (which are the uses for which the FDA cleared those products). However, SPD also challenges a number of specific advertising statements for those products, as well certain statements for FR Analog 5-day and the FR analog home ovulation test.

In its Complaint in the First Action, SPD challenged as false not only the Accurate Digital Results statement on the FR Digital 5-day package, but also the statement on the side-panel of the package that "in clinical testing, FR® detected [hCG] in 58% of women for days

before their expected period . . . ." (Dkt No. 1 ¶43)[8] SPD claimed that this statement is false because, allegedly, FR Digital 5-day is not "effective 4 days before a woman's expected period." (*Id.* ¶44) SPD also challenged as false similar statements made in various other media concerning the ability of FR Digital 5-day to detect pregnancy 5 days before MMP, and the 58% positive detection rate at 5 days before MMP, on the basis that "the claim of effectiveness '5 Days sooner' is false." (*Id.* ¶¶46-52) SPD also challenged as false statements concerning the ability of FR Analog 5-day to detect pregnancy 5 days before MMP. (*Id.* ¶¶61-63)

SPD's Complaint also contained a series of allegations concerning C&D's purported "History of False and Misleading Claims," in which it alleged that various other C&D advertising statements are false and misleading. Although it is not clear from SPD's pleading whether it seeks relief with respect to any of these challenged statements, SPD has had its expert, Dr. Barnhart, offer opinions on at least two of them, so C&D assumes for purposes of this motion that SPD intends to pursue all of these challenges. They are:

- The statement that FR home pregnancy tests detect "a hormone variant that better predicts early pregnancy." (Dkt No. 1 ¶¶27-28)
- The statement on the package of C&D's analog home ovulation test kit, "Get Pregnant Sooner." (*Id.* ¶29; Copies of the product packaging are attached as Ex. F to the Feldman Dec)
- The statement on the package of C&D's analog home ovulation test kit, "New Technology! Better Predicts Ovulation!" (*Id.* ¶30)
- The statement, "If you just can't wait until your missed period to know if you're pregnant or not, there's only one test to choose: First Response®. Let us tell you first." (*Id.* ¶31)
- The "tag line." "Let us tell you first." (*Id.* ¶32)
- The internet domain name, "tellsyoufirst.com." (*Id.*)
- The purportedly misleading "connecting" of the separate statements "5 days sooner" and "99% accurate." ((*Id.* ¶33; *see also* ¶64)

[8] "Dkt No." refers to the ECF docket for Case No. 09-01802 and "2nd Dkt No." refers to the ECF docket for Case No. 10-00276.

In its Counterclaims in the Second Action, SPD also challenged the "Tells You statement and the Unsurpassed Accuracy Statement made on the packaging for FR Analog 6 day. (2nd Dkt No. 4 ¶¶40-42) (copies of the product packaging are annexed as Ex. E to the Feldman Dec.) SPD also challenged several other aspects of C&D's advertising for that product:

- SPD challenged as false the statements on the package for FR Analog 6-day, "NEW" and "Enhanced Technology." (2nd Dkt No. 4 ¶43)
- SPD alleges that C&D "fails to properly explain that it calculates the day of the missed period by a different method than the rest of the industry calculates that date." (*Id.*)
- SPD alleges that C&D "misleads the public by its knowing omission of an explanation of the difference between the day of the 'missed period' and the day of the 'expected period.'" (*Id.* ¶44)
- SPD alleges that the "overall import" of C&D's advertising for FR Analog 6-day is that the "product is superior to all others," and that "this message is false . . . ." (*Id.* ¶45)

ARGUMENT

I. THE LEGAL STANDARDS GOVERNING THIS MOTION

A. The Standards for Summary Judgment

Fed. R. Civ. P. 56(a) provides that a party may move for summary judgment on any claim or defense, or any part of a claim or defense, and that the Court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Whether a disputed fact is material depends on the substantive law at issue. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Relatedly, a factual dispute is "genuine" only if, resolving that dispute in the nonmoving party's favor, "a reasonable jury could return a verdict for the nonmoving party." *Id.*

Critically, where a plaintiff relies on expert testimony to establish an essential element of its case, summary judgment must be granted in favor of the defendant if that testimony is excluded under *Daubert* and Rule 702. *See, e.g., Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 151 (3d Cir. 1999); *Kolokowsk v. Crown Equip. Corp.,* No. 05-4257, 2009 WL 2857957, at *4 (D.N.J. Aug. 27, 2009); *Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 473 (E.D. Pa. 2008); *AstraZeneca LP v. TAP Pharms. Prods.,* 444 F. Supp. 2d 278, 292-293 (D. Del 2006).

B. The Elements of a Lanham Act False Advertising Cause of Action

Liability under the Lanham Act can arise if an advertising statement "is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.,* 627 F. Supp. 2d 384, 463 (D.N.J. 2009) (Wolfson, J.).[9] A literal claim is one that communicates an unambiguous message; in other words, a message that can reasonably be interpreted to mean only one thing. *See, e.g., Bracco*, 627 F. Supp. 2d at 465; *Novartis*, 290 F.3d at 586-587. In analyzing whether a claim is a literal claim (and also whether it is false), it is essential that the challenged advertising statement be considered in the full context in which it appears, because taking a sentence or phrase out of context often materially changes its meaning. *Castrol, Inc. v. Pennzoil Co.,* 987 F.2d 939, 946 (3d Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context"); *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms.*, 19 F.3d 125, 129 (3d Cir. 1994) ("A

[9] In addition to proving the existence of a false or misleading statement, the plaintiff must also prove that (1) the false or misleading statement actually deceived or has a tendency to deceive a substantial segment of the audience for that statement; (2) the deception is material, in that it is likely to influence purchasing decisions; (3) the defendant caused the false statement to enter interstate commerce; and (4) the plaintiff has been or is likely to be injured as a result of the deceptive statement. *See Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms.*, 19 F.3d 125, 129 (3d Cir. 1994); *Bracco*, 627 F. Supp. 2d at 454.

determination of literal falsity rests on an analysis of the message in context"). If a claim is found by the court to be a literal claim, then it is for the finder of fact to determine whether or not it is false without reference to how the consuming public understands the message. *Id.* at 129.

Importantly, it has long been the law in the Third Circuit that, where an advertiser makes a literal statement about product performance, the plaintiff's burden is to prove that the statement is affirmatively untrue, not merely that it is inadequately substantiated. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228 (3d Cir. 1990) ("a Lanham Act plaintiff bears the burden of showing that a challenged advertisement is false or misleading, not merely that it is unsubstantiated by acceptable tests or other proof").

If a court determines that an advertising statement is literally true or ambiguous, a plaintiff cannot prevail on a theory that the statement is deceptive or misleading without evidence of what consumers actually understand the statement to communicate. This almost always requires consumer survey evidence. *Johnson & Johnson-Merck Consumer Pharms. Co.*, 19 F.3d at 129-30 ("If a plaintiff does not prove the claim to be literally false, he must prove that it is deceptive or misleading, which depends on the message that is conveyed to consumers . . . . [T]he success of the claim usually turns on the persuasiveness of a consumer survey"); *Sandoz*, 902 F.2d at 228-29 (if advertisements are not literally false, plaintiff "cannot obtain relief by arguing how consumers could react; it must show how consumers actually do react").

C. SPD's State Law Claims

SPD's pleadings also allege false advertising in violation of New Jersey law (in the Second Action) and California law (in the First Action). The elements of SPD's state law claims for relief are identical to the elements of SPD's Lanham Act claims and, for purposes of this motion, are to be decided as the Lanham Act claims are decided. *See, e.g., Bracco Diagnostics,*

613 F. Supp. 2d at 454; *Buying for the Home, LLC v. Humble Abode, LLC*, 459 F. Supp. 2d 310, 317-18 (D.N.J. 2006); *Rice v. Fox Broad. Co.*, 330 F.3d 1170, 1181-82 (9th Cir. 2003).

II. C&D IS ENTITLED TO SUMMARY JUDGMENT ON SPD'S CHALLENGE TO ITS RIGHT TO MAKE THE 6-DAY AND 5-DAY STATEMENTS

SPD's challenge to the statements that FR Digital 5-day and FR Analog 5-day are effective at detecting pregnancy 5 days before MMP, as well as its challenge to C&D's right to advertise FR Analog 6-day as being capable of detecting pregnancy 6 days before MMP, fail for two reasons. First, as discussed more fully in the accompanying *Daubert* motion, they are all premised on (a) Dr. Barnhart's opinion that C&D miscalculates the day of EMP and (b) the results of SPD clinical testing that did not use C&D's EMP estimation method. As is detailed in the *Daubert* motion, Dr. Barnhart's opinions are not admissible. Thus, SPD has no admissible evidence that Church & Dwight's method for estimating EMP is unreasonable. Nor, accordingly, is there any basis for SPD to challenge the results of C&D's clinical testing using that method by pointing to tests it conducted using a *different* method.

Second, where the FDA has cleared a product to be marketed for a particular intended use or with particular labeling, courts hearing Lanham Act suits based on the allegation that the product is not effective for that use, or that label statements cleared by the FDA are false, have declined to reconsider the FDA's determinations and dismissed the Lanham Act challenges. As some courts have held, second-guessing FDA decision making would be inconsistent with the fact that "no private right of action exists to redress alleged violations of the FDCA [federal Food, Drug, and Cosmetics Act]," the enforcement of which "lies exclusively within the federal government's domain, by way of either the FDA or the Department of Justice." *Summit Tech. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 305 (C.D. Cal. 1996). In *Summit*, the court declined to substitute its judgment for FDA's and held that plaintiff's false advertising claim,

which was "essentially a claim under the FDCA," failed as a matter of law because "[p]laintiff's Lanham Act cause of action would . . . usurp[] the FDA's discretionary role in the application and interpretation of its regulations." *See id.* at 305-06 (internal quotes omitted).

Other courts have similarly held that a plaintiff cannot ask a court, in the guise of a Lanham Act claim, to countermand the findings of the FDA. In *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 U.S. Dist. LEXIS 18180, at *18 (E.D. Mich. Mar. 2, 2010), the manufacturer of a brand name drug sued a competitor under the Lanham Act and state law, alleging that defendant falsely marketed its FDA-approved drug as the "generic equivalent" to plaintiff's brand-named product. The court, noting that the FDA had made a determination of generic equivalency when it approved the drug, dismissed the complaint on the ground that it encroached on the FDA's regulatory authority. The court held (*id.* at *18):

> Plaintiff has not pointed to any statement or advertisement that does not directly implicate the FDA's equivalency determination. Allowing Plaintiff's complaint to proceed necessarily questions the validity of the FDA' decisions. Therefore, the Court declines to entertain Plaintiff's generic-equivalency challenges under the Lanham Act.

Likewise, in *Cytyc Corp. v. Neuromedical Systems*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998), the court held that advertising claims "that comport substantively with statements approved as accurate by the FDA cannot supply the basis" for Lanham Act false advertising claims. Specifically, the court observed (*id.*) that:

> [m]any of [counterclaim-defendant's] statements that [counterclaim-plaintiff] claims are false or misleading are, in fact, consistent with the substantive claims approved by the FDA. . . . Although [counterclaim-defendant's] statements do not correspond precisely to statements that the FDA has approved, the challenged statements discussed above are similar enough to the approved statements for the Court to conclude, as a matter of law, that they are neither false nor misleading.

Similarly, in *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, Nos. 95-7011 (HB), 95-7688 (HB), 1996 WL 280810, at *7

(S.D.N.Y. May 24, 1996), the court denied an injunction and declined to review advertising stating that defendant's product "prevents heartburn in half the time" of plaintiff's product. Although the FDA had not approved that specific statement, it had approved the label directions that were the basis for it -- namely that plaintiff's product should be taken 1 hour before eating and defendant's product should be taken 30 minutes before eating. *See id.* at *7. The court held (*id.* at *13):

> FDA, after careful analysis of the studies and the proposed packaging, returned to the manufacturers the approved labeling for each product. Each of the claims [plaintiff] challenges is based on the package labelling [sic] approved by the FDA for both drugs. Although it is clear that the FDA did not determine on its own volition that [plaintiff's product] must be taken one hour prior to a meal to be effective in reducing the symptoms of heartburn, the FDA presumably relied on the studies which support this claim when it approved package labelling [sic] for [plaintiff's product]. Accordingly, for this Court to now state that [plaintiff] can advertise that [its product] begins to relieve the symptoms when taken 30 minutes prior to a meal, or conversely, to enjoin [defendant] from claiming that [defendant's product] works faster than [plaintiff's product] on the basis of package labelling [sic], would substitute this Court's discretion for that of the FDA in approving package labelling [sic] for over-the-counter medications.

See also Rita Med. Sys., Inc. v. Resect Med., Inc., No. C 05-03291 (WHA), 2006 WL 2038328, at *3-4 (N.D. Cal. July 17, 2006) ("the Lanham Act cannot be used as a circuitous route to challenge determinations of the FDA . . . [T]his Court would not be able to consider a claim as to the veracity of [defendant's advertisements] without unduly converting the Lanham Act claim into a review of an FDA action. Such an analysis is not permitted").

Here, it is undisputed that the FDA cleared FR Analog 6-day for the intended use of detecting "the pregnancy hormone (hCG), in some cases, *as early as 6 days before the missed period (5 days before the expected period)*." (Nazareth Dec. Ex. I)(emphasis added). Similarly, the FDA cleared FR Digital 5-day (and FR Analog 5-day) for the intended use of the "early detection of pregnancy by the lay user *up to five (5) days sooner than the day of the missed period (four (4) days before the day of the expected period)*." (*Id.* Exs. H and F) (emphasis

added). Thus, by arguing that *any* statement that FR Analog 6-day can detect pregnancy 6 days before MMP is false, and by arguing that *any* statement that FR Digital 5-day and FR Analog 5-day can detect pregnancy 5 days before MMP is false, SPD is asking this Court to second-guess the FDA's clearance of the products for their specific intended uses. The cases do not permit this.[10]

III. C&D IS ENTITLED TO SUMMARY JUDGMENT ON SPD'S CHALLENGE TO THE TELLS YOU AND ACCURATE DIGITAL RESULTS STATEMENTS

SPD contended in the preliminary injunction phase of this litigation that the Tells You statement is a literal statement that FR Analog 6-day will tell a woman with "certainty" whether she is pregnant 6 days before MMP. That argument is baseless, as SPD implicitly recognized by commissioning the Ericksen survey. Obviously, the word "certainty" is nowhere mentioned in

[10] We anticipate that in opposition to this motion SPD will argue that the urines used in the clinical testing submitted to FDA were somehow compromised, rendering the results of the testing unreliable. That argument is disingenuous in the extreme. Some of the test urines were supplied to C&D by The University of New Mexico ("UNM"), pursuant to a contract between UNM and C&D. Under that contract, UNM collected urines from women and supplied a portion of the collected samples to C&D for use in its clinical testing. The UMN official in charge of this project was Professor Lawrence Cole, although the evidence is unequivocal that he had no day-to-day involvement with the collection of the urines or supplying the urine samples to C&D. SPD used the discovery process in this litigation to pursue a vendetta against Dr. Cole, who had been a consultant for SPD's corporate predecessor and has more recently consulted for C&D. SPD will no doubt point to an "investigation" of Dr. Cole by UNM which, SPD contends, supposedly concluded that urine samples stored in a laboratory run by Dr. Cole were "unfit for research purposes" (in truth, there was no such conclusion by UNM). The short answer to this attack is that the forum for SPD's allegations about the fitness of the urine samples provided to C&D by UNM is the FDA -- which found the results of clinical testing of those urines to be sufficient to clear the products at issue to be marketed for their intended use -- not this Court. In any event, the purported results of the UNM investigation are inadmissible hearsay (in some cases double hearsay, or worse). Moreover, SPD will be unable to offer any evidence -- because there is none -- that the UNM investigation concerned or involves any findings about the scientific fitness of the urines used by C&D. In short, SPD's allegations about Dr. Cole and the UNM investigation are the quintessential "red herring"; they do not raise a triable issue of fact or otherwise have any relevance to this litigation. And, even if they had any relevance, they would not be affirmative evidence of falsity, but rather only an attack on the adequacy of C&D's substantiation which is not sufficient to meet SPD's burden.

the Tells You statement, or elsewhere on the product package. Moreover, the undeniable purpose of any pregnancy test is to tell a woman whether she is pregnant. And, it is also undeniable that FR Analog 6-day is the only product that the FDA has cleared for the intended use of detecting pregnancy as early as 6 days before MMP. Thus, an entirely reasonable interpretation of the Tells You statement is that the FR Analog 6-day is the only product that a woman can purchase for the purpose of learning whether she is pregnant 6 days before MMP.

Further, as noted in Point I.B, *supra*, the meaning and truthfulness of the Tells You statement must be assessed by reviewing the statement in its full context and not, as SPD would have it, by tearing that statement from the FR Analog 6-day package and analyzing it in a vacuum. Far from telling women that they will know with "certainty" whether or not they are pregnant 6 days before MMP, the side panel of the package (*to which woman are directed at the end of the Tells You statement*) states, explicitly, that "[i]n one study, in 68% of the samples tested, pregnancy could be detected up to 6 days before the day of the missed period" and that "[t]he test *may* detect the pregnancy hormone (hCG), *in some cases*, as early as 6 days before the missed period." (Feldman Dec. Ex. E)(emphasis added). The package then goes on to explain that even if a woman gets a negative result 6 days before MMP, it is still possible that she is pregnant: "Important note regarding negative results: *Some pregnant women will not be able to detect hCG in their urine 6 days before the missed period.* If you test negative before your missed period, but think you may still be pregnant, you should retest again a few days after your missed period." (emphasis added). The package also makes clear that it is possible for there to be false positive results as well, stating: "Important note regarding positive results: Because this test detects very low levels of hCG, there is a small chance that this test will give positive results even if you are not pregnant. Chances of this are greater for women nearing age 40 and older.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care."

Because the Tells You statement does not literally communicate the message alleged by SPD, it must proffer consumer survey evidence. *Johnson & Johnson*, 19 F.3d at 129-30. The Ericksen survey, however, is inadmissible for the reasons discussed in the accompanying *Daubert* motion and, in all events, when properly interpreted dispels any notion that a substantial percentage of consumers understand the Tells You statement in the manner claimed by SPD.

SPD's challenge to the Accurate Digital Results statement as a literal claim of certainty (Dkt No. 7 at 16) is meritless for the same reason. The statement does not include the word "certain" or say that the results will be "100% accurate" or have "perfect" accuracy. Further, as with the Tells You statement, the Accurate Digital Results statement explicitly directs consumers to the side panel of the package for the "details." There consumers are told that in clinical testing FR Digital 5-day detected pregnancy 58% of the time 5 days before MMP. (Feldman Dec. Ex. B) Because the Accurate Digital Results statement is not a literal statement of perfect accuracy, SPD must provide consumer survey evidence supporting it. *Johnson & Johnson*, 19 F.3d at 129-30. As SPD has no such evidence, summary judgment should be awarded to C&D.

IV. C&D IS ENTITLED TO SUMMARY JUDGMENT DISMISSING SPD'S CHALLENGE TO THE UNSURPASSED ACCURACY STATEMENT

SPD's argument that the Unsurpassed Accuracy statement is literally false is far from clear. In its withdrawn preliminary injunction motion, SPD contended that it literally referred to accuracy on the day of EMP. (2nd Dkt No. 42 at 11) But that argument is absurd when the Unsurpassed Accuracy statement is viewed in the context of the package on which it is made. The FR Analog 6-day package does not say a word about how the product performs on the day of EMP. In the context of that package, which only addresses the product's performance *6 days*

before MMP, any argument that the Unsurpassed Accuracy statement unambiguously communicates how the product performs *on the day of EMP* is baseless. SPD has offered no consumer survey evidence to support this interpretation.

SPD's latest argument, courtesy of Dr. Barnhart, is that C&D has not proven that the accuracy of FR Analog 6-day at the 6 days before MMP time point is unsurpassed by other products. Dr. Barnhart says that the clinical testing referenced on the side panel of the FR Analog 6-day package is a sensitivity study as opposed to an accuracy study, and that the latter also requires that one take into account the rate of false positive results.

This argument is wrong, and misconceives SPD's burden of proof. FR Analog is, indisputably, the only product FDA has cleared for the intended use of detecting pregnancy as early as 6 days before MMP. That alone is sufficient to enable C&D to claim unsurpassed accuracy 6 days before MMP. In any event, SPD can only prevail by proving the Unsurpassed Accuracy statement to be affirmatively false, not merely inadequately substantiated. (*See* Point I.B, *supra*.) Thus, SPD would have to demonstrate that another product is more accurate than FR Analog 6-day at the 6 days before MMP time point. SPD has no such evidence.

V. C&D IS ENTITLED TO SUMMARY JUDGMENT ON SPD'S CHALLENGE TO THE STATEMENT THAT THE FR PRODUCTS "DETECT A HORMONE VARIANT THAT BETTER PREDICTS EARLY PREGNANCY"

As for SPD's challenge to the statement that the FR pregnancy tests detect "a hormone variant that better predicts early pregnancy," SPD alleges only that it "is unsubstantiated (and in fact is incapable of substantiation)." (Dkt No. ¶27) The hormone variant in question is known as hyperglycosylated hCG ("HhCG"). In his expert reports, Dr. Barnhart does not allege that the statement is false, but argues only that it cannot be substantiated. Again, a plaintiff cannot meet its burden of proof merely by arguing that an advertising statement lacks adequate substantiation. *Sandoz*, 902 F.2d at 228. In none of his expert reports did Dr. Barnhart contend that the

challenged statement is actually false. Indeed, during his deposition he declined to opine that (a) HhCG does not exist in early pregnancy (Vinti Dec. Ex. 15 at 376-377)) or (b) the FR pregnancy test kits do not detect HhCG in urine (*id.* 377-379). And, in any event, there *is* substantiation for this advertising statement -- scientific proof shows that the FR pregnancy tests *do* detect HhCG and that HhCG *is* prevalent in early pregnancy urines. (Gronowski Dec. ¶¶8-12)

Presumably, Dr. Barnhart's opinions on this point were purposefully crafted to invoke the Third Circuit's holding in *Novartis*, 290 F.3d at 590, that "a court may find that a *completely unsubstantiated* advertising claim by the defendant is *per se* false without additional evidence from the plaintiff to that effect." The key, as *Novartis* makes clear, is that there be *absolutely no substantiation* for the challenged advertising statement. *See, e.g., Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp.3d 594, 607 (D.N.J. 2003) (relying on *Novartis* and stating that defendant had "not one scintilla of evidence to support" the challenged advertising claim). Here, as noted, there *exists* evidence substantiating the challenged statement. Just because Dr. Barnhart disagrees that the substantiation is scientifically valid neither renders the statement "completely unsubstantiated" nor satisfies SPD's burden to prove that it is false.

VI. C&D IS ENTITLED TO SUMMARY JUDGMENT ON SPD'S OTHER CHALLENGES TO NON-LITERAL ADVERTISING STATEMENTS

All of the other statements about C&D's home pregnancy and ovulation products challenged by SPD are either not literal statements of product performance (and in no case does SPD have the required consumer survey evidence) or are non-actionable puffery:

- SPD challenges the statement "*Get Pregnant Sooner*" for the FR analog home ovulation test, which it says is "unsubstantiated." (Dkt No. 1 ¶29) Here again, SPD cannot meet its burden of proof by arguing that there is not sufficient substantiation. *Sandoz*, 902 F.2d at 228-29.

SPD also calls on Dr. Barnhart to support this challenge.[11] Although, he does not contend that the product is ineffective in detecting the likely time of ovulation, he (and thus SPD) nonetheless complain that:

> "Get Pregnant Sooner" "*implies that* C&D's . . . test does more than point to the best days to have intercourse in order to conceive. It implies that C&D's product will somehow biologically enhance a woman's physical ability to conceive. This is simply not the case, with C&D's home ovulation test or any other.

(Vinti Dec. Ex. 12 at 37)(emphasis added). As Dr. Barnhart (and thus SPD) concede in the above-quoted language, the allegedly false message is not literally stated, but only "implied." SPD needs a consumer survey to prove the claimed implied communication. *Johnson & Johnson. Co.*, 19 F.3d at 129-30. It does not have one.

- SPD challenges the statements "NEW" and "Enhanced Technology" for FR Analog 6-day, which SPD alleges are "falsely" made (2nd Dkt No. 4 ¶43)). This appears to be a reference to the product packaging, which when the product was launched bore a banner that reads "NEW" and a separate banner that reads "Enhanced Technology." (Feldman Dec. Ex. E) Similarly, SPD challenges the statements "New Technology!" and "Better Predicts Ovulation," which were made on the FR home ovulation test. (2nd Dkt No. 4 ¶30) SPD alleges these statements about the ovulation test are false because the technology is not "new" and "the statement claims superiority that is unsubstantiated." (*Id.*)

The fact is that, as is detailed in Dr. Nazareth's accompanying declaration, FR Analog 6-day is a "new" product with "enhanced" technology as compared to previously-marketed

[11] The discussion of ovulation tests in his expert report actually shows why the challenged statement *is* substantiated. As Dr. Barnhart explains (Vinti Dec. Ex. 12 at 37): a home ovulation test "informs a woman" as to when she is likely to ovulate, "and intercourse during this time *will optimize her chances of conception.*" (emphasis added). Thus, a woman who uses a home ovulation test to time when she has intercourse is, as a matter of biology and simple logic, likely to "get pregnant sooner" than a woman who does not use a home ovulation test for that purpose.

products. (Nazareth Dec. ¶17) SPD thus cannot meet its burden of proving falsity. Likewise, the technology referenced on the FR analog ovulation test kit package was also "new" (Nazareth Dec. ¶39) and SPD has no evidence to the contrary. Finally, "Better Predicts Ovulation" is not a literal claim of superiority in comparison to competing products. (An example of a literal superiority statement would be "Predicts Ovulation Better Than Clearblue.") Rather, to the extent there is any comparative message at all, it is to the prior version of the FR product, and that comparison is truthful. (*Id.*) To prove that any other message is communicated, SPD needs a survey (*Johnson & Johnson. Co.*, 19 F.3d at 129-30) and it does not have one.

- SPD challenges the statement, "If you just can't wait until your missed period to know if you're pregnant or not, there's only one test to choose: First Response®. Let us tell you first" (which SPD characterizes as an "explicit superiority claim" that, it says, is "flatly false" because FR is not the only brand "that detects pregnancy prior to" MMP) (2nd Dkt No. ¶31). It also challenges the "tag line," "Let us tell you first" (which SPD interprets as claiming that FR products "predict pregnancy earlier than other products") (*id.* ¶32) and the internet domain name, "tellsyoufirst.com" (which SPD alleges "communicates falsely that the FR products are superior to other products, including Clearblue Easy, in detecting pregnancy early"). (*Id.*)

To begin with, the "If you just can't wait" statement is not a literal claim that FR is the only pregnancy test brand capable of detecting the pregnancy hormone prior to MMP (the statement is not, for example, "only FR can detect pregnancy before the day of a woman's missed period"). Thus, to prove the implied message argued by SPD, it needs consumer survey evidence (*Johnson & Johnson. Co.*, 19 F.3d at 129-30), and it has none. Moreover, the phrase "there's only one test to choose" could be reasonably interpreted as a generalized endorsement of FR pregnancy test kits as "the best" among other products that can detect early pregnancy. That

message constitutes non-actionable puffery. *See Castrol*, 987 F.2d at 945 ("Puffery is an exaggeration or overstatement expressed in broad, vague, and commendatory language…[It] is distinguishable from misdescriptions [sic] or false representations of specific characteristics of a product. As such it is not actionable.")

The challenged tag line, "Let us tell you first," also does not make a literal claim of superior product performance. It is, literally, *a request* by C&D for consumers to purchase FR pregnancy test products. Again, consumer survey evidence is needed (*Johnson & Johnson. Co.*, 19 F.3d at 129-30) and, again, SPD has none.

Finally, the domain name "tellsyoufirst.com" does not even identify a particular product or type of product, much less constitute a literal message of superiority. Again, there is no consumer survey evidence to support the meaning SPD alleges.

- SPD complains about the purported "connection" of 5-days and 6-days sooner statements with statements of 99% accuracy on the day of EMP, which SPD alleges "leads consumers to the false conclusion that the product is 99% accurate" prior to the day of EMP. (Dkt No. 1 ¶33; *see also* 2nd Dkt No. ¶38). In no case, however, has C&D made a literal statement that any of its pregnancy test products are 99% accurate prior to the day of EMP; SPD can point to no advertising where a statement of 99% accuracy is stated to be or depicted as being at a point in time before the day of EMP. Thus, this challenge is to a purported implied message for which SPD has no survey evidence.

- SPD complains about Church & Dwight's purported "failure" "to properly explain that "C&D calculates the day of the missed period by a different method than the rest of the industry calculates that date" (2nd Dkt No. ¶44) and the purported "knowing omission" on the FR Analog 6-day product package of an explanation of the difference between the day of the

'missed period' and the day of the 'expected period.'" (*Id.*) As is obvious, these challenges do not involve any statement at all, but rather allegations of misleading omissions.[12] There is no survey evidence to support SPD's allegations of deception.

CONCLUSION

For the reasons discussed herein and in C&D's accompanying *Daubert* motion, C&D respectfully requests that the Court grant its motion for summary judgment in full.

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[12] The same is the case for SPD's allegation that the "overall import" of C&D's advertising for FR Analog 6-day is that the product "is superior to all others, including Clearblue," when it is really (according to SPD) "inferior to others, including Clearblue . . ." (2nd Dkt No.4 ¶45) By definition, a challenge about the "overall import" of multiple, separate advertising statements is not an allegation that a specific advertising statement is literally false.